General

Guideline Title

Best evidence statement (BESt). Patient/family satisfaction and safety of self-infusion of subcutaneous gamma-globulin.

Bibliographic Source(s)

Cincinnati Children's Hospital Medical Center. Best evidence statement (BESt). Patient/family satisfaction and safety of self-infusion of subcutaneous gamma-globulin. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2011 Feb 15. 4 p. [7 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

The strength of the recommendation (strongly recommended, recommended, or no recommendation) and the quality of evidence (1a-5) are defined at the end of the "Major Recommendations" field.

It is recommended that patients receiving subcutaneous gamma-globulin (SCIg) at home, being administered by a nurse, be allowed to choose to do self administration of SCIg in the home after training is complete (Chapel et al., 2000 [2b]; Gardulf et al., 2006 [4a]; Gardulf et al., 2004 [4a]; Gasper, Gerritsen, & Jones, 1998 [4b]; Kittner et al., 2006 [4b]; Ochs et al., 2006 [3a]; Zampelli, 2007 [5]).

Definitions:

Table of Evidence Levels

Quality Level	Definition
1a† or 1b†	Systematic review, meta-analysis, or meta-synthesis of multiple studies
2a or 2b	Best study design for domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5	Other: General review, expert opinion, case report, consensus report, or guideline

†a = good quality study; b = lesser quality study

Table of Recommendation Strength

Strength	Definition
"Strongly recommended"	There is consensus that benefits clearly outweigh risks and burdens (or vice-versa for negative recommendations).
"Recommended"	There is consensus that benefits are closely balanced with risks and burdens.
No recommendation made	There is a lack of consensus to direct development of a recommendation.
Dimensions: In determining the strength of a recommendation, the development group makes a considered judgment in a consensus process that incorporates critically appraised evidence, clinical experience, and other dimensions as listed below.	
1. Grade of the body of evidence 2. Safety/harm 3. Health benefit to the patients (direct benefit) 4. Burden to patient of adherence to recommendation (cost, hassle, discomfort, pain, motivation, ability to adhere, time) 5. Cost-effectiveness to healthcare system (balance of cost/savings of resources, staff time, and supplies based on published studies or onsite analysis) 6. Directness (the extent to which the body of evidence directly answers the clinical question [population/problem, intervention, comparison, outcome]) 7. Impact on morbidity/mortality or quality of life	

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Conditions requiring subcutaneous gamma-globulin infusion

Guideline Category

Management

Clinical Specialty

Allergy and Immunology

Family Practice

Internal Medicine

Pediatrics

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To evaluate, among patients receiving subcutaneous gamma-globulin (SCIg) in the home, if self infusion or infusion by caregiver versus infusion by a Home Care nurse, increases family satisfaction with no decrease in safety

Target Population

Home care patients, greater than 10 kg, who require subcutaneous gamma-globulin infusion, and their caregivers, who choose to learn home-administration, upon physician approval

Interventions and Practices Considered

Administration of subcutaneous gamma-globulin by self infusion, infusion by caregiver or infusion by home care nurse

Major Outcomes Considered

- Family satisfaction
- Safety

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Search Strategy

Databases searched included CINAHL, MEDLINE, and PubMED between 1991 to 2008. Keywords included: subcutaneous, gamma-globulin, safety, adverse reactions, children, pediatric, adult, and patient satisfaction.

Number of Source Documents

Seven articles were relevant to the population, intervention, comparison, outcome (PICO) question. These seven articles were critically appraised, leveled, and graded.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Table of Evidence Levels

Quality Level	Definition
1a† or 1b†	Systematic review, meta-analysis, or meta-synthesis of multiple studies
2a or 2b	Best study design for domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5	Other: General review, expert opinion, case report, consensus report, or guideline

†a = good quality study; b = lesser quality study

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Not stated

Rating Scheme for the Strength of the Recommendations

Table of Recommendation Strength

Strength	Definition
"Strongly recommended"	There is consensus that benefits clearly outweigh risks and burdens (or vice-versa for negative recommendations).
"Recommended"	There is consensus that benefits are closely balanced with risks and burdens.
No recommendation made	There is a lack of consensus to direct development of a recommendation.
Dimensions: In determining the strength of a recommendation, the development group makes a considered judgment in a consensus process that incorporates critically appraised evidence, clinical experience, and other dimensions as listed below.	
1. Grade of the body of evidence 2. Safety/harm 3. Health benefit to the patients (direct benefit) 4. Burden to patient of adherence to recommendation (cost, hassle, discomfort, pain, motivation, ability to adhere, time)	

Strength	Definition
	5. Cost-effectiveness to healthcare system (balance of cost/savings of resources, staff time, and supplies based on published studies or onsite analysis) 6. Directness (the extent to which the body of evidence directly answers the clinical question [population/problem, intervention, comparison, outcome]) 7. Impact on morbidity/mortality or quality of life

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

Reviewed against quality criteria by two independent reviewers.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Chapel HM, Spickett GP, Ericson D, Engl W, Eibl MM, Bjorkander J. The comparison of the efficacy and safety of intravenous versus subcutaneous immunoglobulin replacement therapy. J Clin Immunol. 2000 Mar;20(2):94-100. PubMed

Gardulf A, Nicolay U, Asensio O, Bernatowska E, Bock A, Carvalho BC, Granert C, Haag S, Hernandez D, Kiessling P, Kus J, Pons J, Niehues T, Schmidt S, Schulze I, Borte M. Rapid subcutaneous IgG replacement therapy is effective and safe in children and adults with primary immunodeficiencies--a prospective, multi-national study. J Clin Immunol. 2006 Mar;26(2):177-85. PubMed

Gardulf A, Nicolay U, Math D, Asensio O, Bernatowska E, Bock A, Costa-Carvalho BT, Granert C, Haag S, Hernandez D, Kiessling P, Kus J, Matamoros N, Niehues T, Schmidt S, Schulze I, Borte M. Children and adults with primary antibody deficiencies gain quality of life by subcutaneous IgG self-infusions at home. J Allergy Clin Immunol. 2004 Oct;114(4):936-42. PubMed

Gaspar J, Gerritsen B, Jones A. Immunoglobulin replacement treatment by rapid subcutaneous infusion. Arch Dis Child. 1998 Jul;79(1):48-51. PubMed

Kittner JM, Grimbacher B, Wulff W, Jager B, Schmidt RE. Patients' attitude to subcutaneous immunoglobulin substitution as home therapy. J Clin Immunol. 2006 Jul;26(4):400-5. PubMed

Ochs HD, Gupta S, Kiessling P, Nicolay U, Berger M, Subcutaneous IgG Study Group. Safety and efficacy of self-administered subcutaneous immunoglobulin in patients with primary immunodeficiency diseases. J Clin Immunol. 2006 May;26(3):265-73. PubMed

Zampelli AR. Improving quality of life at home for pediatric patients and families with primary immune deficiencies using subcutaneous immunoglobulin infusions. Home Health Care Manag Pract. 2007;19(6):431-5.

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Increased satisfaction for patients and caregivers who are able to control the time for administration of subcutaneous gamma-globulin (SCIg) may result in greater compliance, which would increase health benefits.

Potential Harms

Evidence showed no serious adverse effects with the administration of subcutaneous gamma-globulin (SCIg).

Qualifying Statements

Qualifying Statements

This Best Evidence Statement addresses only key points of care for the target population; it is not intended to be a comprehensive practice guideline. These recommendations result from review of literature and practices current at the time of their formulation. This Best Evidence Statement does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this Statement is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Cincinnati Children's Hospital Medical Center. Best evidence statement (BESt). Patient/family satisfaction and safety of self-infusion of subcutaneous gamma-globulin. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2011 Feb 15. 4 p. [7 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Feb 15

Guideline Developer(s)

Cincinnati Children's Hospital Medical Center - Hospital/Medical Center

Source(s) of Funding

Cincinnati Children's Hospital Medical Center

Guideline Committee

Not stated

Composition of Group That Authored the Guideline

Group/Team Leader: Lucy O'Quinn, BSN, RNII, CPN, Home Health Care

Other Group/Team Members: Mary Baker, RN II, Home Health Care; Vicki Richardson, BSN RN, Home Health Care; Lynn Lednik, RN II, CPN, Home Health Care; Julie Elfers, RN II, CPN, Home Health Care; Lois Siegle, BSN RN II, CPN, Home Health Care; Lyn King BSN, RN, CPN, Home Health Care; Marilyn Poynter, RN, C Psych., Home Health Care

Support Personnel: Barbara K. Giambra, MS, RN, CPNP, Evidence-Based Practice Mentor, Center for Professional Excellence-Research and Evidence-Based Practice

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the Cincinnati Children's Hospital Medical Center Web site .

Print copies: For information regarding the full-text guideline, print copies, or evidence-based practice support services contact the Cincinnati Children's Hospital Medical Center Health James M. Anderson Center for Health Systems Excellence at EBDMInfo@cchmc.org.

Availability of Companion Documents

The following are available:

- Judging the strength of a recommendation. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2008 Jan. 1 p. Available from the Cincinnati Children's Hospital Medical Center Web site .
- Grading a body of evidence to answer a clinical question. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 1 p. Available from the Cincinnati Children's Hospital Medical Center Web site .
- Table of evidence levels. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2008 Feb 29. 1 p. Available from the Cincinnati Children's Hospital Medical Center Web site .

Print copies: For information regarding the full-text guideline, print copies, or evidence-based practice support services contact the Cincinnati Children's Hospital Medical Center Health James M. Anderson Center for Health Systems Excellence at EBDMInfo@cchmc.org.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on January 4, 2012.

Copyright Statement

Disclaimer

NGC Disclaimer

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion-criteria.aspx.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.